K101986

9.0 510(K) SUMMARY

SEP - 9 2011

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT
Asahi Intecc Co., Ltd.
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Japan

OFFICIAL CORRESPONDENT
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TRADE NAME: ASAHI ULTIMATEbros 3 PTCA Guide Wire

COMMON NAME: Guide Wire

CLASSIFICATION NAME: Wire, Guide, Catheter

DEVICE CLASSIFICATION: Class 2 per 21 CFR §870.1330

PRODUCT CODE DQX

PREDICATE DEVICE:
Asahi - JoWire Neo's PTCA Guide Wire - 510(k) K022762
Asahi - JoWire Asahi PTCA Guide Wire - 510(k) K031277
Asahi - ASAHI PTCA Guide Wire - 510(k) K070945
Asahi - ASAHI PTCA Guide Wire J shape series - 510(k) K043422
Asahi - ASAHI PTCA Guide Wire Confianza Pro - 510(k) K041531
Asahi - ASAHI PTCA Guide Wire - 510(k) K032615

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The ASAHI ULTIMATEbros 3 PTCA Guide Wire is a steerable guide wire with a maximum diameter of 0.014 inches (0.36mm) and available in 180 cm and 300 cm length. The guide wire is constructed from a stainless steel core wire with platinum-nickel coil. The coil part (distal end) of the guide wire has a radiopaque to achieve visibility. The distal end of the coil part is available straight and is made soft to easily bend with the vessel curve, or available as a pre shaped "J ".

A hydrophilic coating is applied to the coil part (distal portion) of the guide wire. The proximal section of the guide wire is coated with PTFE, and the PTFE in the proximal coating is available in two types - PTFE type I and type II.

INDICATION FOR USE:

The ASAHI ULTIMATEbros 3 PTCA Guide Wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The ASAHI ULTIMATEbros 3 PTCA Guide Wire is not to be used in the cerebral blood vessel.

TECHNICAL CHARACTERISTICS:

Comparisons of the ASAHI ULTIMATEbros 3 PTCA Guide Wire and predicate devices show that the technological characteristics such as product performance, design and intended use are substantially equivalent to the current marketed predicate devices.

The device modification for the ASAHI ULTIMATEbros 3 PTCA Guide Wire is modification in the guide wire coating - application of hydrophilic coating and additional PTFE coating, minor dimensional changes in distal core wire tip of the guide wire and addition of J tip shape of the guide wire.

The ASAHI ULTIMATEbros 3 PTCA Guide Wire is similar in design - device dimensional specifications, and intended use, manufacturing process, operating principle, shelf life and sterilization process are the same and materials that have been used in other predicate devices in that its core wire, tip coils and solders remain the same.

PERFORMANCE DATA:

All components that come in direct contact with the patient have a long history of use in medical devices and are proven to be biocompatible for use in the vasculature.
The biocompatibility testing as listed below was leveraged from predicate devices with identical materials and manufacturing process.
This submission contains reference to predicate ASAHI devices that use the same materials as used in the subject device, and also includes evaluations that the test results of biocompatibility for materials of the predicate devices are able to apply to the subject device. And In vitro bench testing and shelf-life testing, including tensile strength, torque strength, torqueability, tip flexibility, coating adherence, catheter compatibility and integrity (particulate testing) as listed below were conducted on the subject device - ASAHI ULTIMATEbros 3 PTCA Guide Wire. This 510(k) notice includes mechanical and functional bench testing that demonstrates that the ASAHI ULTIMATEbros 3 PTCA Guide Wire performs as intended.

Performance test/evaluation summary:
Device performance:
Tensile Strength
Turns to Failure (Torque Strength)
Torqueability (Torque Response)
Tip Flexibility
Coating Adhesion
Slipping Ability of Guide Wire in PTCA Balloon Catheter
Particulate testing

Biocompatibility:
Systemic Toxicity Study
In Vitro Hemolysis Study
Intracutaneous Study
Cytotoxicity Study
Sensitization Study
Pyrogen Study
Plasma Recalcification Time Coagulation Study
In Vivo Thromboresistance Study
C3a Complement Activation Study
SC5b-9 Complement Activation Study

SUMMARY/CONCLUSION:

The ASAHI ASAHI ULTIMATEbros 3 PTCA Guide Wire characteristics are substantially equivalent to the specified predicate devices and other currently marketed devices for the same indication for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Asahi Intecc USA, Inc.
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2500 Red Hill Avenue, Suite 210
Santa Ana, CA 92705

SEP - 9 2011

Re: K101986
Trade/Device Name: ASAHI ULTIMATEbros 3 PTCA Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: August 25, 2011
Received: September 8, 2011

Dear Mr. Terai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K101986

Device Name: ASAHI ULTIMATEbros 3 PTCA Guide Wire

Indications for Use:

The ASAHI ULTIMATEbros 3 PTCA Guide Wire is intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). The ASAHI ULTIMATEbros 3 PTCA Guide Wire is not to be used in the cerebral blood vessel.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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